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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,813	07/22/2003	En Li	0609.4560003/KRM/DJN	2332

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WASHINGTON, DC 20005

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,813	Applicant(s) LI ET AL	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 14-23 and 38-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 11, 12, 14-23 and 38-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

1. Applicants are put on notice that each sequence, SEQ ID number and ATCC Deposit number reads on an independent and distinct invention and that is reflected in the following requirement.
2. Claim 23 cites an acronym, DNMT3. Applicants are requested to identify this acronym's corresponding sequence. If Applicants elect a Group with this acronym and in the event several sequences are encompassed by this acronym Applicants may receive another Election/Restrictions Requirement.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I-VI. Claims 11 and 12, drawn to an isolated polypeptide, respectively, classified in class 530, subclass 350.
 - VII. Claims 14 and 15, drawn to a method for diagnosing or determining a susceptibility to neoplastic disorders, classified in class 435, subclass 7.1. Claim 14 will be examined with this Group to the extent the method implements assaying *de novo* DNA cytosine methyltransferase protein with an antibody.
 - VIII. Claims 14 and 16, drawn to a method for diagnosing or determining a susceptibility to neoplastic disorders, classified in class 435, subclass 6. Claim 14 will be examined with this Group to the extent the method implements assaying *de novo* DNA cytosine methyltransferase mRNA .

Art Unit: 1643

- IX. Claim 17, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. 209933, classified in class 530, subclass 350.
- X. Claim 18, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. 209934, classified in class 530, subclass 350.
- XI. Claim 19, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. 98809, classified in class 530, subclass 350.
- XII. Claim 20, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. 326637, classified in class 530, subclass 350.
- XIII. Claim 21, drawn to an isolated *de novo* DNA cytosine methyltransferase Dnmt3b polypeptide, which is SEQ ID NO: 2, classified in class 530, subclass 350.
- XIV. Claim 22, drawn to an isolated *de novo* DNA cytosine methyltransferase DNMT3B polypeptide, which is SEQ ID NO: 4, classified in class 530, subclass 350.
- XV. Claim 23, drawn to a method of screening for an agonist/antagonist of DNMT3, classified in class 436, subclass 86.
- XVI and XVII. Claims 38-42 and 45-49, drawn to an isolated nucleic acid molecule, respectively, classified in class 536, subclass 23.1.

Art Unit: 1643

XIII. Claim 43, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. PTA-4611, classified in class 530, subclass 350.

XIX. Claim 44, drawn to an isolated *de novo* DNA cytosine methyltransferase polypeptide having the amino acid sequence encoded by the cDNA clone, ATCC Deposit No. PTA-4610, classified in class 530, subclass 350.

XX and XXI. Claim 50, drawn to a method for in vitro *de novo* methylation of DNA comprising contacting said DNA with a *de novo* DNA cytosine methyltransferase polypeptide and purifying said DNA, respectively, classified in class 436, subclass 174.

XXII and XXIII. Claims 51-55, drawn to an isolated nucleic acid molecule, respectively, classified in class 536, subclass 23.1.

4. The inventions are distinct, each from the other because of the following reasons: Groups I-VI, IX-XIV, XVI-XIX, XXII and XXIII are structurally and functionally different products, which are made by different methods and have different uses. In the instant case, the nucleic acids of Groups XVI, XVII, XXII and XXIII are deoxyribonucleic acids (DNA), unbranched polymers composed of four subunits. The proteins of Groups I-VI, IX-XIV, XIII and XIX are a linear order of amino acid residues. Nucleic acid products and polypeptide products are made by different methods.

The methods of Groups VII, VIII, XV, XX and XXI differ in the method objectives, method steps and parameters and in the reagents used.

The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Invention XV and Inventions XVI, XVII, XXII and XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the polynucleotides of Inventions XVI, XVII, XXII and XXIII are not required for the method group of Invention XV and are not useable or searchable together.

Inventions XX and XXI and Inventions IX-XIV, XIII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, any of the polypeptides of Inventions IX-XIV, XIII and XIX could be used in the methods of Groups XX and XXI.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Art Unit: 1643

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Art Unit: 1643

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

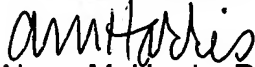
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

20 June 2006